

A COMPARATIVE STUDY OF SHORT OUTCOME RESULTS BETWEEN HIP SPICA CAST AND TITANIUM ELASTIC INTRAMEDULLARY NAIL FOR ISOLATED FEMORAL SHAFT FRACTURES IN CHILDREN AGED BETWEEN 4-6 YEARS

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Received date: 06 September 2021

Revised date: 26 September 2021

Accepted date: 16 October 2021

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ABSTRACT

Background: Femoral shaft fractures are among the most common fractures that required hospitalization in children. There is no agreement about the best treatment options in preschool aged. **Objectives:** The aim of the study to compare prospectively between Hip Spica Cast and Titanium Elastic Nails regarding hospital stay, union, recovery period, final functional outcome, family satisfaction and complications for femoral shaft fracture in children aged between 4-6 years. **Patients and method:** A total of 40 patients, age between 4 to 6 years with isolated femoral shaft fractures were divided equally into two groups, group A treated by spica casting, group B treated by titanium elastic nail during the period from august 2019 to December 2020 at Al-Jumhoori teaching hospitals with follow up period of 6 months scheduled at 2, 6, 12 and 24 weeks. **Results:** This study showed comparable result in hospital stay (2.3/2.2) days $P=0.3$ and union time (6.9/6.8 weeks $P=0.6$) between spica cast and titanium elastic nail respectively. A statistically significant differences were noted in independent walking (8.9/7.1 weeks) and returned to activities (10.6/8.6 weeks) between spica cast and titanium elastic nail respectively. Significant P value of 0.002 and <0.0001 respectively. According to Flynn's criteria excellent to satisfactory result (80%) in spica cast patients and (95%) of the patients had excellent to satisfactory results in titanium elastic nail significant P value =0.01. **Conclusion:** Spica cast and titanium elastic nail are good treatment options for pediatrics femoral fractures. This study revealed that TEN had shorter recovery time, better parents satisfaction and functional outcome scores than spica cast.

KEYWORDS: femoral fracture, titanium elastic nail, spica casting.

INTRODUCTION

A pediatric femoral shaft fracture is the most common major pediatric orthopedic injury. Femur fractures account for 1.6% of all pediatric fractures.^[1] Femur fractures are more common in boys than in girls Unlike adults, most femur fractures in children are shaft fractures, followed by distal and then proximal fractures. The injury mechanism depends on the child's age, etiology of injury includes falls, motor vehicle related, sports injuries and abuse.^[2,3] Pediatric shaft femur fractures are 2.6 times more common in boys than in girls. A bimodal distribution has been distinguished, with the 1st peak occurring in the toddler years and the 2nd peak during early adolescence period.^[1] Minor trauma or repetitive fractures should alert the clinician to the

possibility of an underlying pathologic condition, such as osteogenesis imperfecta. Generalized osteopenia from cerebral palsy, myelomeningocele, and other neuromuscular conditions also predisposes to fracture.^[4] The most common benign conditions include aneurysmal bone cyst, unicameral bone cyst, nonossifying fibroma and eosinophilic granuloma.^[5] Age is the chief predictor of treatment, other factors like fracture type, weight, related injuries can also guide treatment. Femur fractures management has evolved significantly over the last 50 years. Nonoperative treatment with traction and immobilization was before the mainstay of treatment, however because of a need for rapid recovery and rehabilitation of the patients, with the recognition of morbidity that associated with long immobilization may

have negative effects even in children, in addition the development of several fixation devices management geared toward operative treatment.^[6] In children 1-5 years of age, hip spica casting has traditionally been the treatment of choice unless there are concomitant injuries, excessive shortening (>2cm), swelling and skin complications which can prevent application of hip spica.^[7] Hip spicas were arbitrarily classified into "immediate" and "early" spicas based on the timing of the application of the spica. If the spica is applied within the first 24 hours of presentation, it is called "immediate spica casting" whereas it is referred to as "early spica casting" when the spica is applied a few days after the injury.^[7] The optimum position for the application of hip spica has always been controversial. According to a recent Cochrane review, the effective and safe position is 30° of abduction, 30° to 40° of flexion and 10° to 20° external rotation at the hip.^[8] It has also been observed that knee flexion greater than 60° improves maintenance of length and reduction. The fracture location may also determine the amount of flexion needed at hip with more proximally positioned fractures requiring more amount of flexion and abduction.^[9] Other studies have reported good outcomes for 'one and a half' hip spica casting in the 90-90 position/ "sitting spica cast".^[10] The Flexible Intramedullary Nail (FIN) developed by the Nancy group in France, this is the most popular method of fracture fixation in the age group of 5-11 years old with length stable fracture in patient of weight less than 50 kg.^[11] Flexible intramedullary nailing allows a biological environment that enhances both the rate of fracture healing and the quantity of callus formation. This is achieved by minimizing periosteal stripping through a minimally invasive approach and in most cases a closed reduction. The insertion of the nails done either through antegrade or retrograde fashion.^[12]

PATIENTS AND METHODS

Prospective randomized case series study is carried out in Al-Jumhoori teaching hospital, The study was conducted from August 2019 to December 2020. Children between 4-6 years with Simple closed displaced femoral shaft fracture are included in this study and we excluded patients with comminuted, intra articular fracture, open fractures, polytraumatized, patients with metabolic bone disease or pathologic fractured, patients more than 25 kg or refused participate in this study, A total number of 40 patients were included, Patients were divided into two groups. Each group consisted of 20 patients, group A treated by Hip Spica and group B by closed Titanium Elastic Intramedullary Nailing, The patients selections were made on random basis (every other case). All patients were admitted to the emergency department and kept under observation and were checked by other surgical teams to be sure that there was no other injuries. Fall from more than 6 feet and RTA considered as high energy trauma, While fall on ground and sport injuries considered as low energy trauma. Intravenous line, analgesia and skin traction applied for all patients

Fig. (1), I.V. fluid and urinary catheter inserted in some patients, all patient sent for blood investigation (Hb%, virology test and and COVID 19), in addition to appropriate antero-posterior and lateral plain radiography included the injured limb, joint above and below and pelvis according to the severity or mechanism of the trauma. Assessment of limb, vascular and neurological conditions repeated during the 24 hours.



Fig. (1). show skin traction.

Details about each treatment methods, approach and possible complications were discussed with the families. Verbal and written consent was obtained for each patient before starting treatment. All the patients in both groups were treated within the first 72 hours from the injury, and were kept in the surgical ward after that for 24 hours post-operatively. According to severity of trauma, stable general condition, swelling and fractures displacement, The spica cast applied either immediately or delayed for two to three days (early spica cast). Application of the cast undertaken under GA using cotton, fiberglass cast or Plaster of Paris and warm water, one and half leg cast were applied for all patients by aid of Spica table Fig. (2). Under GA Closed reduction done under fluoroscopic guidance (on radiolucent table) until most proper reduction and alignment achieved the (Table 1), patient then transferred to the spica table gently. With assistant hold the fracture in reduced position cotton applied from nipple to the metatarsal phalangeal joint of the fractured limb and to just below the knee of contralateral side. Abdomen, chest and bony prominences were padded carefully (by cotton or gauze) to avoid maceration and sores of the skin. One and half spica applied from proximal to distal, the cast applied from the xiphosternum or just below it to both knees first and left to harden in position of 30° to 40° of hip flexion, about 30° to 40° abduction and 15° external rotation, more proximal fracture need more hip flexion and abduction with gentle leg traction to hold reduction, valgus molding at the fracture site was sometimes applied (in proximal and middle third fractures) to prevent varus malunion. Then cast applied over the knee to the midfoot of the fractured limb in about 60° of knee flexion and neutral flexion of ankle. The cast then reinforced at the groin and buttock to avoid breakage. After the cast settled and harden, the patient transferred again to the operative table for trimming of the cast ends and the final fluoroscopic images were taken to check for fracture site position in both Antero-Posterior and lateral view.



Fig. (2). A. Cotton and fiberglass cast B. Water C. Spica table, D. One and half hip spica for 4.5 years male with left midshaft femoral fracture.

Postoperatively patients admitted to the surgical ward for 24 hours under observation to check for neurovascular status and cast syndrome. After discharge, patients follow up schedule was on 2, 6, 12 and 24 weeks postoperatively to check for fracture alignment, cast condition, radiological union, weight bearing and returned to activities after cast removal and joints movement. Cast was removed after 6 - 8 weeks after radiological union achieved. In group B the operation done either next morning or after two days according to patients general condition or operative theater preparations. Operative time was measured from closed reduction to the final shot of fluoroscopy in the Spica cast and to the application of the dressing in the TEN

patients. Third generation Cephalosporin 50mg/kg was given I.V in the ward about one hour before the operation, with respect to any associated drug allergy in every patient, they received aminoglycoside (gentamicin injection 6 mg/kg/day single dose only) instead. Under general anesthesia, supine position on radiolucent table or sometimes orthopedics table. Under fluoroscopic guidance manipulation and closed reduction of the fractures attempted Sterilization and draping the patient injured limb leaving the thigh exposed from hip to knee, small medial and lateral incision about 1-2 cm long were made in distal thigh about 2-3 cm above the knee joint line marked under fluoroscopy as in Fig.(3).

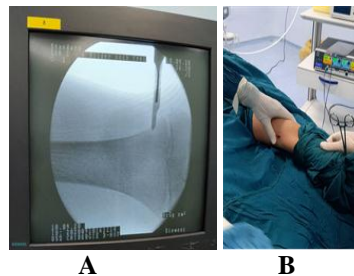


Fig.(3). Show A: incision done under fluoroscopic guidance, B: Skin incision in distal thigh about 1 cm long.

Small holes (medial and lateral) were made in the distal metaphyseal cortex about 2 cm above the physal line using Awl or drill (3.2 or 3.5mm) directed in 90°, then

lower the drill or Awl to about 45° toward the opposite cortex Fig.(4).

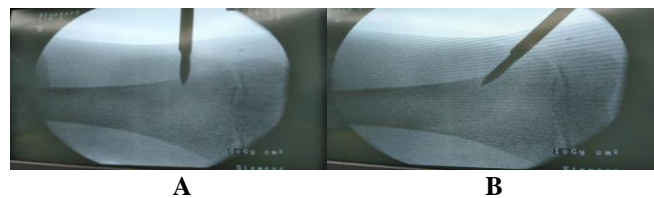


Fig.(4). Show A:awl perpendicular to the cortex, B: awl 45° to the cortex.

Nails size were chosen according to Flynn by measuring the narrowest diameter of the femoral medullary canal (isthmus) x 0.4, two largest fitted nails of the same size should be use. The elastic nails used in this study were of size 3 and 2.5 mm in diameter. After measuring the approximate distance from the insertion site to the fracture site, the elastic nail was gently bended (usually about 25° - 30°) so that the convex surface lying at the fracture level. Fixed the prepended nail into the T Handle

with the bended tip marked to a fixed point in the inserter (this can help to know the direction of the nail in the medullary cavity and reduce exposure to fluoroscopic images). Using the T-Handle the nails introduced first in 90° and then lowered to 45° with the bended tip directed towarded the fracture, and with rotation movement of the wrist both nails introduce to the femoral canal in retrograde fashion (aid with fluoroscopy both AP and lateral view) to just before the fracture line Fig.(5).

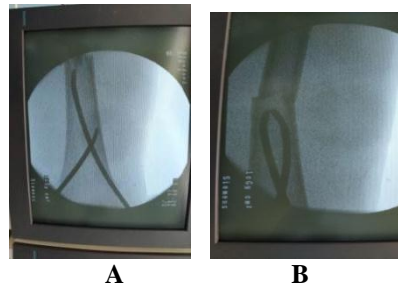


Fig.(5). A. Introduce the elastic nail into medullary cavity first nail push to the fracture line B both nails pushed to the fracture line.

With the fracture held in reduced position further advancement of the nails to the proximal fragment under image intensifier was done, the proximal bended tips adjusted in the medullary cavity and the nails pushed further toward the proximal spongy femoral metaphysis with fluoroscopic guide Fig.(6). Both nails should crossed over again after they passed the fracture, during nails advancement care must be taken not to wind one

rod around the other by avoidance rotating them more than 180° around their axis, Cut the nails ends in 2cm long distal to the cortex at the insertion site and bended them under the skin, the final 1cm of nails advancement can be done with gentle hammering without passing through the proximal femoral physis or cortex penetration.



Fig.(6). Both nails pushed toward the proximal dense metaphysis of the femur.

Fracture stability was checked before and after nails trimming and the wounds were closed with non-absorbable sutures, none of our patients required temporal casting support. Patients were nursed in supine position with the operated side elevated on a pillow and were kept in the surgical ward to check for any postoperative complications. Oral A.B and simple analgesia were prescribed for 3 to 4 days postoperatively. Patients' mobilization started in the first week postoperatively but without weight bearing. Follow up

schedule by researcher was made on 2, 6, 12 and 24 weeks. In the follow up visits the patients assessed for infection, entry sits problems, alignment, radiological and clinical union, shortening, mobilization, activity and hip and knee movement,. Partial weight bearing encouraged at four to five weeks postoperatively according to patients tolerances and full weight bearing by six to eight weeks depending on radiological callus formation and fracture configuration.

Table 1: Acceptable angulation and shortening according to age.^[1]

Age/years	Varus-valgus angulation (degree)	Anterior-posterior angulation(degree)	Shortening (mm)
0 – 2	30	30	15
2 – 5	15	20	20
6 – 10	10	15	15
11 – maturity	5	10	10

The final results in both treatment modalities were classified according to Flynn's score. Table 2.

Table 2: Flynn's criteria for femoral fracture management outcome score.^[1]

Results at 4–6 months	Excellent	Satisfactory	Poor
Limb discrepancy	<10 mm	<20 mm	>20 mm
Mal alignment	<5°	5-10°	>10°
Pain	None	None	Present
Other complications	None	Minor and resolved	Present and lasting

The data were statistically analyzed using SPSS/PC software version 23, chi squar test and t test for

comparing categorical data and means respectively. P value less than 0.05 is considered statistically significant.

RESULTS

In this study 40 patients with isolated displaced femoral shaft fracture age between 4 and 6 years were included in the study and were divided equally into two groups.

Mean age in the group A was 4.98 years and group B was 5.05 years, P value= 0.5. Mean weight in group A was 17.22 kg and in group B was 17.30 kg, P value= 0.6 Sex distribution are shown in Fig.(7). P= 0.5

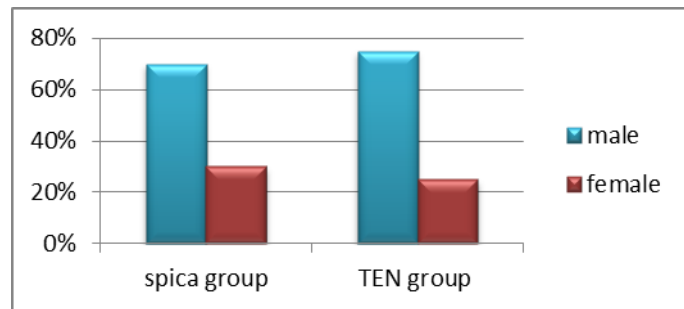


Fig.(7) : Sex distribution in TEN and Spica groups.

In group A 70% male, 30% female In group B 75% male, 25% female Fractures side distribution in this study is shown in Fig.(8). P= 0.5

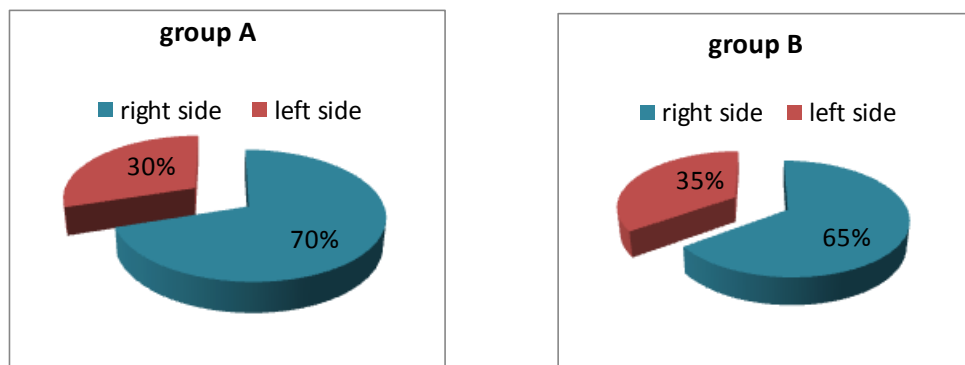


Fig.(8): Fracture side distribution in TEN and Spica groups.

In group A 70% right side, 30% left side In group B 65% right side, 35% left side Fracture morphology distribution are shown in Fig.(9). P 0.5

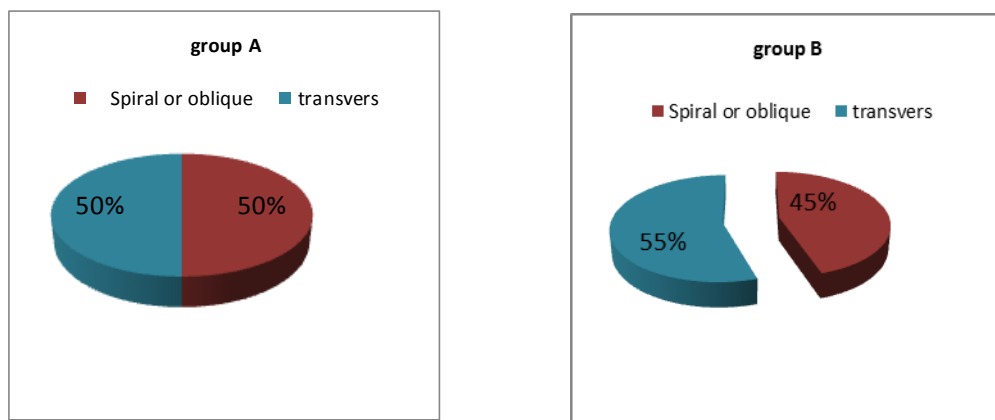


Fig.(9): Femur fracture morphology.

In group A 50% transvers, 50% oblique and spiral In group B 55% transvers, 45% oblique and spiral

Percentage of mechanism of injuries are referred in Fig.(10). P= 0.5

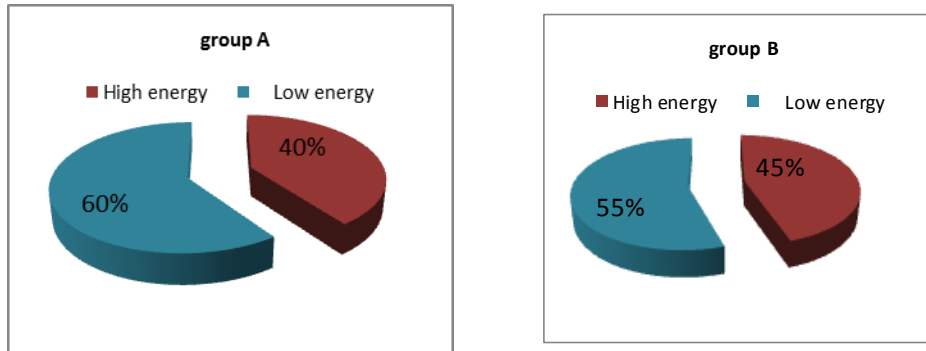


Fig.(10): Percentage of injuries mechanism.

In group A 40% high energy, 60% low energy In group B 45% high energy, 55% low energy, Midshaft fracture

was the dominant in both groups and the percentage of fracture site are shown in Fig.(11). P= 0.7

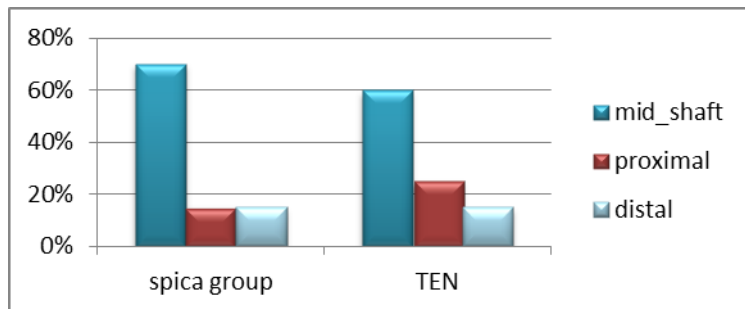


Fig.(11): Percentage of fractures sites distribution.

In group A 70% midshaft, 15% proximal, 15% distal, In group B 60% midshaft, 25% proximal, 15% distal. Hospital stay for group A was between 1-4 days with mean time of 2.38±0.5 days and for the group B was 2-3 days with mean time of 2.25±0.50 days, insignificants P

value of 0.3. The study showed that operative time for group A was between 13 - 23 minutes mean time of 16.95±2.95 minutes, while the operative time for group B was between 40-60 minutes and mean time of 49.05±5.11 minute, Table 3. significant P<0.0001

Table 3: Hospital stay and operative time in both group.

Variable	Group	Results	Mean	P Value
Hospital stay	Spica	1 - 4 days	2.38±0.5	0.3
	TEN	2 - 3 days	2.25±0.4	
Operative time	Spica	13 – 23 min	16.95±2.95	<0.0001
	TEN	40 – 60 min	49.05±5.11	

Clinical union defined by no pain, tenderness or movement at fracture site. Radio logically callus formation on three cortices at fracture site on both AP and lateral views. In this study all the patients developed union, non-had delayed or nonunion, in group A union was between 6 to 8 weeks with mean time of 6.95±0.9 weeks, while in group B union was between 5 to 8 weeks with mean time of union was 6.8±1 weeks, insignificant P=0.6 Independent walking in group A was between 8 to 10 weeks, with poor compliance in one patient who had significant knee complaint and started full independent walk at 12 weeks post-operatively. In group B patients started independent walking between 6 to 8 weeks postoperatively. Mean time to independent walk in group A was 8.9±1.3 and in TEN group was 7.1±0.8 with a significant P= 0.002. Statically significant difference was also in return to full activities, patients in group A were fully active between 10-14 weeks, while patients in

group B returned to full activities between 10-12 weeks postoperatively. The mean time of returned to full activities was 12.1±1.65 in group A and 10.5±0.8 in group B, with significant P = 0.0005. Table 4.

Table 4: Time to union, independent walk and full activities.

Variable	Group	Results in wks	Mean	P Value
Union	Spica	6 - 8	6.95± 0.9	0.6
	TEN	5 - 8	6.8± 1	
Independent walk	Spica	8 -12	8.9 ± 1.3	0.002
	TEN	6 - 8	7.1 ± 0.8	
Full activities	Spica	10 -14	12.1±1.6	0.0005
	TEN	10-12	10.5 ± 0.8	

In group A malalignment out of accepted limits was recorded in one patient (5%) who had midshaft spiral

fracture Fig.(12). united in 17° varus and 15° of anterior angulation.

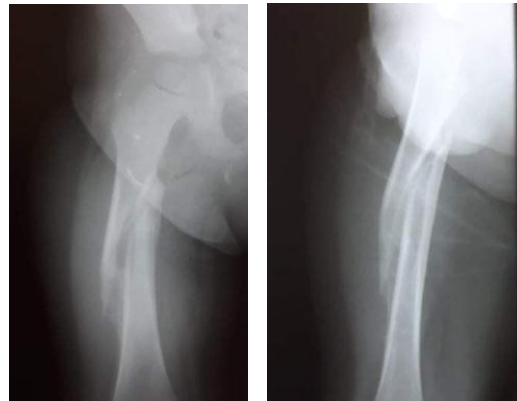


Fig.(12): significant shortening in 4 years child treated with hip spica.

In group A the coronal plane angulation was between 17° varus - 5° valgus), sagittal plane angulation was between 15° anterior – 5° posterior. Shortening out of acceptable limits in group A reported in two patients (10%), one with transvers fracture united in overlapped position and shortening of 20 mm, the other patients with spiral fracture united in varus and anterior angulation and shortening of 23 mm. Four patients in this group had shortening between 10-15mm while the rest of the patients had either no shortening or shortening <10mm. In group B malalignment out of acceptable limits was not

recorded. coronal plane angulation was ranging between 8° varus to 3° valgus, while the sagittal angulation was between 13° anterior – 0° posterior. No clinically significant shortening recorded in TEN patients, shortening was reported in four patients all were <10mm, in the other hand we had 2 patients developed lengthening one with spiral midshaft and the other with transvers midshaft fracture. Both of them had lengthening less than 5 mm. The final outcome results at 6 months in both groups were classified according to the Flynn's criteria Table 5.

Table 5: Results classification according to Flynn's criteria.

Results at 6 months	Spica N=20	TEN N=20	P Value
Excellent	10 (50%)	17 (85%)	0.01
Satisfactory	6 (30%)	2 (10%)	
Poor	4 (20%)	1 (5%)	

In Spica patients satisfactory results were due to shortening between 10-20 mm or due to malalignment between 5°-10° in either sagittal or coronal plans. Poor results were due to shortening more than 20mm or due to malalignment >10° in either sagittal or coronal plans. In

TEN patients satisfactory results were due to malalignment between 5°-10° in either sagittal or coronal plans. Poor results in one patient with sagittal malalignment of 13° anterior. Table 6.

Table 6: complications classified by Modified Clvaie- Dindo Classification.

clavien-Dindo	definition	SPICA (N= 20)	TEN (N = 20)	P Value
Grade 1	complication without deviation in routine follow up	Not recorded	1	
Grade 2	deviation from routine follow up like increase	5	7	

	visits or outpatients treatment			
Grade 3	complications that need surgical intervention or anesthesia	1	2	
Grade 4	Limb or life threatening, permanent deficit	Not recorded	Not recorded	
Grade 5	Death	Not recorded	Not recorded	
total patients		5 (25%)	7 (35%)	0.04

In the **group A**, Grade 2 complications consisted of a limb with LLD of more than 20 mm in one patient, 1 patient with knee stiffness, one patient with skin

dermatitis around perineum and one pressure site over the heel Fig.(13), one patient need cast wedging.



Fig.(13). Show heel irritation pressure site.

Grade 3 complications consisted of one patient with repeated cast UGA due to loss of reduction after 2 weeks Fig.(14).



Fig.(14). reduction loss after 2 week in patient with hip spica cast.

In **group B**, grade 1 complication in one patient with fever in the second week post operatively, Grade 2 complication consisted of two patients with superficial

infection treated with one week of oral antibiotics and five patients with knee discomfort and nails insertion sites irritations Fig.(15).



Fig.(15). Show insertion site skin irritation.

Grade 3 complications consisted of nail ends trimming at 4 months post operatively in one patient with bursitis near nail insertion site. A simple survey was done for the parents or care givers showed that 19 parents or

caregivers (95%) were satisfied about the treatment method in TEN patients Fig.(16). while only 13 care givers or parents (65%) were satisfied in spica group.



Fig.(16). Radiography show excellent alignment of femoral fracture treated with TEN in 6 years girl.

DISCUSSION

Femoral fractures in preschool children have a great probability of remodeling and rapid union rate, a non-anatomical immobilization is also accepted and have an affinity to heal without long term sequels.^[13] Although hip spica casting is a safe and effective treatment for many pediatric femoral shaft fracture the associated complications, such as skin irritations, malunion, joint stiffness, and prolonged immobilization, are common.^[13] Recently, ESIN has been advocated by many studies for treating pediatric femoral shaft fractures. Although many studies have compared ESIN and spica casting in several countries, only a few have been conducted in Iraq.^[14,15] The mean time to union in group A was 6.9 weeks and in group B was 6.8 weeks which is insignificant, such insignificant results also encountered in Heffernan et al which compared femoral fracture union in children between 2 _ 6 years of age in Mars 2015.^[16] Statistically significant results between these treatment methods was found in returned to full activity and full independent ambulation.in group A mean time to independent walking was longer than group B with significant P value of 0.002 Time to returned to full activities was also shorter in group B compared to group A, P value was 0,0005. Such results was also found in Heffernan et al, the TEN group had shorter time to independent walking and return to full activities.^[16] This short recovery times between the two treatment groups was probably attributable to the fact that the group B children commenced weight bearing once the pain stopped before achieving radiographic union, whereas it is difficult to keep them on non-weight bearing once they feel pain-free. Patients in group A was kept immobilized until there was evidence of radiographic union at an average of approximately 7 weeks In this study, according to Flynn,s criteria TEN patients had higher score compared to hip spica patients, this can be explained by that SPICA patients had more degrees of malalignment and shortening compare to TEN patients. Such higher score in TEN group were found in studies by Saseender^[17] and Ramo et al.^[18] Skin problems encountered in two patients (10%) in group A. This agree with Illgen et al of (15%)

incidence of skin complications.^[19] Infection was reported in 2 cases in group B (10%) this agree with study conducted by Muni et al^[20] which conducted 8.3% infection rates. 5 of the patients (25%) had nails sites irritation this is comparable with a study by Kawalkar and Badole^[21] who found 18% of insertion site irritation in their study, but was higher than Salem et al^[22] which reported only 4%. This can be clarified by this study used the bending technique of the distal nails ends and leaving them somewhat long to be removed easily later on. In general complications was higher in TEN patients than SPICA patients, however these complications were all transient without long term sequelae except for one patient in group A with 23 mm shortening that required long follow up. Such High TEN complications also found in Ramo et al^[18] in their comparative study of children 4 and 5 years with femoral shaft fractures in 2016. Study by Kumar et al^[23] found that complications in SPICA patients was higher than TEN patients but this study included older patients between 5-15 years with high percentage of malalignment and shortening in SPICA patients.^[23] This study showed the mean hospital stay was longer in group A (although it was not significant) but this longer hospital stay is agree with other studies conducted Hawaizi et al and Ruhullah et al which showed hospital stay was longer in spica patients.^[15,24] In our study parents satisfaction was as high as 95% in comparison to 65% in spica group. Shemshaki et al.^[25] in 2011 also reported higher satisfaction of parents in TEN patients compared to Hip spica patients.^[24], early mobilization and short recovery course, low care burden on the family, good fractures alignment, mild LLD in TEN patients compare to SPICA patients can explained this difference in family satisfaction.

CONCLUSIONS AND RECOMMENDATIONS

Titanium Elastic Nailing and Spica cast are fairly good options for treatment of pediatric Femoral fracture aged between 4-6 years. Patients in TEN group had short recovery course and higher families satisfaction compared to hip spica patients This study showed

radiological, clinical benefit and functional outcome score favoring TEN over Spica casting, Families and doctors shared treatment options, advantages and disadvantages is advised. This study is not without limitations. The results would have been much validated with a longer follow up period and a larger sample size.

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